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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,167	BILLING-MEDEL ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,10,12-14 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,10,12-14 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the papers filed August 4, 2004. Currently, claims 7, 10, 12-14, 16 are pending.

2. Any objections and rejections not reiterated below are hereby withdrawn.

3. This action contains new grounds of rejection necessitated by amendment.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 7, 10, 12-14, 16 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The claims are drawn to isolated polypeptides having at least 85% identity with SEQ ID NO: 41-49 and fragments thereof having a length of at least 15 amino acids. The claims are also drawn to antibodies that specifically bind to a polypeptides where the polypeptide has at least 85% identity to an amino acid sequence of SEQ ID NO: 41-49 and fragments thereof. Also, methods of making polypeptide and antibodies are claimed.

The specification asserts that the polypeptides may be used to detect, diagnose, stage, monitor, prognosticate, prevent, treat, or determine predisposition to disease and conditions of the GI tract such as cancer (page 1, lines 12-15). The organs of the GI

tract include the esophagus, stomach, small and large intestines, rectum and pancreas (page 1, lines 16-17).

The specification teaches ESTs were derived from cDNA libraries from GI tract tumor tissue, GI tract non-tumor tissues and numerous other tissues (page 51). The consensus sequence was found more than 82 times more often in GI tract than non GI tract tissues (page 51, lines 30-35). This statement does not discuss the presence or frequency of normal expression vs cancerous expression or diseased expression. Example 4 is directed to ribonuclease protection assay, but no results are provided. Example 5 is directed to Northern Blotting but no results are provided. The additional examples are all drawn to methods well known in the art for studying genetic material, however there are no particular studies or assays performed using SEQ ID NO: 41-49. It is noted that SEQ ID NO: 41 is 917 amino acids in length. SEQ ID NO: 42-49 range from 15 amino acids to 40 amino acids in length.

The post-filing date art teaches polypeptides within the scope of the claims which have very significantly divergent functions. For example, WO200168848 teaches a amino acid sequence, namely SEQ ID NO: 258 which is 99.6% identical to SEQ ID NO: 41. Amino acid positions 1-917 of SEQ ID NO: 41 of the instant application and positions 1-919 of SEQ ID NO: 258 of '848 are 99.6% identical (see attached alignment). The nucleic acid is taught to encode PRO polypeptides which are used to diagnose the presence of tumors such as colon, lung and prostate.

Additionally, WO9963088 teaches a polypeptide, namely SEQ ID NO: 258 sequence which 99.7% identical to SEQ ID NO: 41which is described as having identity

with a chloride channel protein and lung-endothelial cell adhesion molecule-1 that encodes a novel polypeptide. Amino acid positions 1-917 of SEQ ID NO: 41 of the instant application and positions 1-919 of SEQ ID NO: 258 of '088 are 99.6% identical (see attached alignment).

WO2003005024 teaches an amino acid sequence, namely SEQ ID NO: 1, which is 99.8% identical to SEQ ID NO: 41 of the instant application. The 917 amino acids are aligned. The CLCA4 protein is applicable to diagnosis and screening drugs for pulmonary and chest disease accompanied by inflammation in lung or airway and respiratory disease.

WO200214366 teaches an amino acid sequence of hCLCA4 (Figure 14) which is 99.8% identical with SEQ ID NO: 41. The 917 amino acids are aligned. The document teaches that the gene is involved in immune related responses observed with asthma.

US20020160382 teaches that a polypeptides, for example SEQ ID NO: 54, which is 99.9% identical is expressed in colon cancer. The 917 amino acids are aligned. It is clear from the post filing date art, that amino acids which are very similar to SEQ ID NO: 41, are not useful for the same properties. The post filing date evidence does not appear to support the assertion that the instant amino acids may be used to detect, diagnose, stage, monitor, prognosticate, prevent, treat, or determine predisposition to disease and conditions of the GI tract such as cancer.

In the event that the polypeptides could be used to detect, diagnose, stage, monitor, prognosticate, prevent, treat, or determine predisposition to disease and conditions of the GI tract such as cancer (page 1, lines 12-15), this would not be a

specific utility, as the GI tract encompasses very large numbers of diseases and conditions which the specification has not specifically pointed out. The statement in the specification regarding the general diagnostic utility for GI tract diseases is not sufficient since the specification has not disclosed what diseases may be diagnosed.

Further, the claimed polypeptides are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a polypeptide can be used to obtain an antibody. The antibody could then be used in conducting research to functionally isolate the protein. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case, none of the antibodies that are to be produced as final products resulting from processes involving claimed polypeptides have specific and substantial utilities. The research contemplated by applicant(s) to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. While the specification provides numerous studies which may be performed to determine the function and identity of the proteins claimed, the specification fails to provide any particular evidence to the function of the biological material. The skilled artisan would be required to perform further experimentation to reasonably confirm a "real world" context of use for the proteins and antibodies. The basic research required would be to study the properties of the claimed product itself to determine the

mechanisms in which the material is involved. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context of use. Given the instant specification, there is no evidence the proteins are involved in the GI tract diseases, or how they may be used to diagnose/detect GI tract diseases. Prior to using the instant invention, the skilled artisan would be required to study the basic properties of the claimed invention to determine how to use the claimed invention in a meaningful and useful way. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. It is noted that the post-filing date art which encompasses the claimed polypeptides and antibodies does not support the utility of diagnosing GI tract disorders.

Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility of the utility has not been assessed.

Further experimentation would be required of the skilled artisan to determine a use for the polypeptides of the claimed invention. As noted by Brenner v. Manson, 383 US 519, 535-536 (1996), "Congress intended that no patents be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use - testing... a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

Response to Arguments

The response traverses the rejection. The response asserts that the post-filing date references cited by the examiner did not clearly state which sequences the examiner is referring to and provide an alignment. While the examiner had prepared the alignments for mailing, it does not appear that the alignments were mailed. Alignments are thus being mailed attached to the instant office action. In the event that applicant does not receive the alignments or has further questions, applicant is requested to contact the examiner so the issue may be resolved.

The response asserts that one of ordinary skill in the art would be able to differentiate GI cancer from a normal healthy state of an individual or other types of cancer and this would be considered specific disease. This argument has been thoroughly reviewed, but is not found persuasive because the instant specification has provide no guidance in using the instant polypeptides or fragments for detecting GI cancer. The specification has provided no guidance of overexpression, underexpression or mere detection as indicative of GI cancer. It is acknowledged that a definitive result need not be obtained by using the polypeptide, however the instant specification has provide no guidance as to how to use the polypeptide for detecting or verifying cancer development as suggested by the instant response (page 7).

With respect to applicants assertion that detecting the polypeptides in the circulation of patients at distant sites can be sued as an indicator of disease of the tract, this appears to be attorney arguments. MPEP 716.01(c) makes clear that "The arguments of counsel cannot take the place of evidence in the record. In re Schulze , 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements

which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long - felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant." Here, the statements regarding the operability of the polypeptide in detection of the protein in distant sites as an indicator of diseases of the tract must be supported by evidence, not argument.

The response asserts that antibodies against the claimed polypeptides proves that the polypeptides have a substantial utility. The response further asserts that detection of these complexes is an indication of the presence of CS193 antigen (page 8 of response filed August 4, 2004). This argument has been thoroughly reviewed, but is not found persuasive because detection of the CS193 does not appear to have a specific or substantial utility. Detection of the CS193 antigen does not appear to be indicative of any particular disease or condition. Thus, applicants have not provided any guidance about how to use the detection of CS193.

Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 112- Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 7, 10, 12-14, 16 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404, "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention

The claims are drawn to isolated polypeptides having at least 85% identity with SEQ ID NO: 41-49 and fragments thereof. The claims are also drawn to antibodies that specifically bind to a polypeptides where the polypeptide has at least 85% identity to an amino acid sequence of SEQ ID NO: 41-49 and fragments thereof. Also, methods of making polypeptide and antibodies are claimed. The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The breadth of the claims

The claims encompass any polypeptides with at least 85% identity, fragments or polypeptides minimally comprising a fragment of SEQ ID NO: 41-49. It is noted that SEQ ID NO: 41 is 917 amino acids in length. SEQ ID NO: 42-49 range from 15 amino acids to 40 amino acids in length. Therefore the claims further broadly encompass polypeptides which minimally contain 15 amino acids or minimally contain fragments of these polypeptides.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since determination of the polypeptides and antibodies would require, initially, in vitro studies to demonstrate proof of principle. That is, prior to any diagnostic or prognostic use, it would be necessary to determine how to make and use the claimed invention. The genus of genetic molecules encompassed by the claims is enormous. To begin experimentation, the skilled artisan would likely begin by determining how to use SEQ ID NO: 41. The specification suggests using the polypeptide in diagnosis, treatment or prediction of GI tract diseases.

The organs of the GI tract include the esophagus, stomach, small and large intestines, rectum and pancreas (page 1, lines 16-17). Thus, GI tract diseases encompass cancers of the esophagus, stomach, small and large intestines, rectum and pancreas, or Crohn's disease, acid reflux problems, bowel movement disorders, etc. There are innumerable additional disease which are commensurate in scope with GI tract disorders.

While one could conduct additional experimentation to determine whether, e.g., presence, expression or amount of a polypeptide which has at least 85% identity with SEQ ID NO: 41-49 or a fragment thereof might be associated with, e.g., certain GI tract

disorders, the outcome of such research cannot be predicted and such further research and experimentation are both unpredictable and undue.

The unpredictability of the art and the state of the art

The post-filing date art teaches polypeptides within the scope of the claims which have very significantly divergent functions. For example, WO200168848 teaches a amino acid sequence, namely SEQ ID NO: 258 which is 99.6% identical to SEQ ID NO: 41. Amino acid positions 1-917 of SEQ ID NO: 41 of the instant application and positions 1-919 of SEQ ID NO: 258 of '848 are 99.6% identical (see attached alignment). The nucleic acid is taught to encode PRO polypeptides which are used to diagnose the presence of tumors such as colon, lung and prostate.

Additionally, WO9963088 teaches a polypeptide, namely SEQ ID NO: 258 sequence which 99.7% identical to SEQ ID NO: 41which is described as having identity with a chloride channel protein and lung-endothelial cell adhesion molecule-1 that encodes a novel polypeptide. Amino acid positions 1-917 of SEQ ID NO: 41 of the instant application and positions 1-919 of SEQ ID NO: 258 of '088 are 99.6% identical (see attached alignment).

WO2003005024 teaches an amino acid sequence, namely SEQ ID NO: 1, which is 99.8% identical to SEQ ID NO: 41 of the instant application. The 917 amino acids are aligned. The CLCA4 protein is applicable to diagnosis and screening drugs for pulmonary and chest disease accompanied by inflammation in lung or airway and respiratory disease.

WO200214366 teaches an amino acid sequence of hCLCA4 (Figure 14) which is 99.8% identical with SEQ ID NO: 41. The 917 amino acids are aligned. The document teaches that the gene is involved in immune related responses observed with asthma.

US20020160382 teaches that a polypeptides, for example SEQ ID NO: 54, which is 99.9% identical is expressed in colon cancer. The 917 amino acids are aligned. It is clear from the post filing date art, that amino acids which are very similar to SEQ ID NO: 41, are not useful for the same properties. The post filing date evidence does not appear to support the assertion that the instant amino acids may be used to detect, diagnose, stage, monitor, prognosticate, prevent, treat, or determine predisposition to disease and conditions of the GI tract such as cancer.

Working Examples

The specification has no working examples, whatsoever, of expression of SEQ ID NO: 41-49 or fragments thereof in tissues of GI tract disorders as compared to normal tissues.

Guidance in the Specification.

The specification, while providing a general review of various methods for detecting protein expression does not provide teachings sufficient to overcome doubts raised in the art. No specific teachings regarding the use of the particular SEQ ID NO: 41-49 with any success is presented. No teachings are provided to demonstrate to the skilled artisan how to use the sequences. It would essentially be a trial and error process to make and use the diverse species of polypeptide molecules encompassed by the claims, and to use them satisfactorily. The teachings of the specification do not establish that one could actually detect SEQ ID NO: 41-49, proteins which are 85%

identical to SEQ ID NO: 41-49, or fragments thereof as an indicator of GI tract diseases. Rather the teachings in the specification merely teach that the consensus sequence and fragments were found in 0.35% of the other, non-GI tract, libraries in the database. This does not provide any indication of the frequencies of the proteins in diseased vs normal tissues to provide guidance to the skilled artisan how to use the proteins to detect, diagnose, treat GI tract disorders. Further there is no indication of which GI tract disorders these proteins would be reasonably able to predispose, diagnose or treat an individual.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, the level of unpredictability in the art is high, the specification provides one with no written description or guidance that leads one to a reliable use the polypeptides and antibodies. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of any working examples and the negative teachings in the art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Response to Arguments

The response traverses the rejection. The response asserts that the claimed invention is enabled for the reasons argued above. This argument has been reviewed but is not convincing for the reasons set forth above. Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 7, 10, 12-14, 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to isolated polypeptides having at least 85% identity with SEQ ID NO: 41-49 and fragments thereof. The claims are also drawn to antibodies that specifically bind to a polypeptides where the polypeptide has at least 85% identity to an amino acid sequence of SEQ ID NO: 41-49 and fragments thereof. Also, methods of making polypeptide and antibodies are claimed.

It is noted that SEQ ID NO: 41 is 917 amino acids in length. SEQ ID NO: 42-49 range from 15 amino acids to 40 amino acids in length. Therefore the claims further broadly encompass polypeptides which minimally contain 15 amino acids or minimally contain fragments of these polypeptides.

The post-filing date art teaches polypeptides within the scope of the claims which have very significantly divergent functions. For example, WO200168848 teaches a amino acid sequence, namely SEQ ID NO: 258 which is 99.6% identical to SEQ ID NO: 41. Amino acid positions 1-917 of SEQ ID NO: 41 of the instant application and positions 1-919 of SEQ ID NO: 258 of '848 are 99.6% identical (see attached alignment). The nucleic acid is taught to encode PRO polypeptides which are used to diagnose the presence of tumors such as colon, lung and prostate.

Additionally, WO9963088 teaches a polypeptide, namely SEQ ID NO: 258 sequence which 99.7% identical to SEQ ID NO: 41which is described as having identity with a chloride channel protein and lung-endothelial cell adhesion molecule-1 that encodes a novel polypeptide. Amino acid positions 1-917 of SEQ ID NO: 41 of the instant application and positions 1-919 of SEQ ID NO: 258 of '088 are 99.6% identical (see attached alignment).

WO2003005024 teaches an amino acid sequence, namely SEQ ID NO: 1, which is 99.8% identical to SEQ ID NO: 41 of the instant application. The 917 amino acids are aligned. The CLCA4 protein is applicable to diagnosis and screening drugs for pulmonary and chest disease accompanied by inflammation in lung or airway and respiratory disease.

WO200214366 teaches an amino acid sequence of hCLCA4 (Figure 14) which is 99.8% identical with SEQ ID NO: 41. The 917 amino acids are aligned. The document teaches that the gene is involved in immune related responses observed with asthma.

US20020160382 teaches that a polypeptides, for example SEQ ID NO: 54, which is 99.9% identical is expressed in colon cancer. The 917 amino acids are aligned. It is clear from the post filing date art, that amino acids which are very similar to SEQ ID NO: 41, are not useful for the same properties. The post filing date evidence does not appear to support the assertion that the instant amino acids may be used to detect, diagnose, stage, monitor, prognosticate, prevent, treat, or determine predisposition to disease and conditions of the GI tract such as cancer.

As provided in the Written Description Guidelines, Example 13 directed to protein variants, the specification and the claims do not indicate what distinguishing attributes are shared by the members of the genus. The limits placed upon the number of amino acid substitutions, deletions, insertions and/or addition that may be made to SEQ ID NO: 41-49 is limitless on the ends of the protein. Additionally the claims allow for 15% change between the sequences. Further, based upon the fragment language, the sequences will have very little similarity to the disclosed sequences. It is noted that the claim does not limit fragment to a particular length. Thus, a fragment of SEQ ID NO: 41 may comprise a "M." Thus, the scope of the claim includes numerous structural variants and the genus is highly variant because s significant number of structural differences between genus members is permitted. The claims would read on splice variant proteins, homologous proteins, variant proteins, etc. As evidenced by the post-filing date art, applicant was not in possession of the claimed genus. Although the specification states that these types of changes are routinely done in the art, the specification and the claim do not provide any guidance as to what changes should e

made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general guidance is what is needed. Since the disclosure fails to descry be the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 41-49 alone is insufficient to describe the genus. There is no description of the mutational sites that exist in nature and there is no description of how the structure of SEQ ID NO: 41-49 relates to the structure of any strictly neutral alleles. The general knowledge in the art concerning variants does not provide any indication of how the structure of one allele is representative of unknown alleles. The nature of alleles is such that they are variant structures, and in the present state of the art the structure of one does not provide guidance to the structure of others. The common attributes are not described. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the genus and is insufficient to support the claim.

With regard to the antibody claims, one of skill in the art would have recognized that the spectrum of antibodies which bind to an amino acid sequence having at least 85% identity with SEQ ID NO: 41-49 or a fragment thereof were not implicitly disclosed since the an amino acid sequence having at least 85% identity with SEQ ID NO: 41-49 or a fragment thereof was not thoroughly disclosed or isolated. Indeed, the court in

Enzo Biochem v. Gen-Probe, Inc., 323 F.3d 956, 964 (Fed. Cir. 2002) ("Enzo Biochem II"), stated that "the written description requirement would be met for all of the claims [of the patent at issue] if the functional characteristic of [the claimed invention was] coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed." The court adopted the USPTO Guidelines as persuasive authority for the proposition that a claim directed to "any antibody which is capable of binding to antigen X" would have sufficient support in a written description that disclosed "fully characterized antigens." Synopsis of Application of Written Description Guidelines, at 60, available at http://www.uspto.gov/web/menu/written.pdf (last visited Jan. 16, 2003) (emphasis added). Therefore, based on our past precedent, as long as an applicant has disclosed a "fully characterized antigen," either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen. In cases where applicant fails to disclose the structural elements of the antibody or antigen, the applicant can not attempt to define an unknown by its binding affinity to another unknown. See Randolph J. Noelle v Seth Lederman, Leonard Chess and Michael J. Yellin (CAFC, 02-1187, 1/20/2004)(Interference No. 104,415).

One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Response to Arguments

The response traverses the rejection. The response asserts that the fragment language requires that the fragments are a subunit of the claimed polypeptide sequences, namely SEQ ID NO: 41-49. This argument has been thoroughly reviewed, but is not found persuasive because the claims are not limited to fragments consisting of at least 15 amino acids from SEQ ID NO: 41-49. The claims merely require that fragments are at least 15 amino acids. Thus, the claims still encompass every polypeptide of more than 15 amino acids.

The response further argues that Applicants have provided a complete structure of the claimed polypeptides as demonstrated in SEQ ID NO: 41-49. This argument has been thoroughly reviewed, but is not found persuasive because the claims are not only drawn to SEQ ID NO: 41-49. The claims are drawn to at least 85% identity with amino acid sequence and also to fragments comprising at least 15 amino acids. Thus, applicants have not described the full structure, but merely a partial structure.

With respect to applicants arguments directed to variants described by the passage in the art. This argument has been thoroughly reviewed, but is not found persuasive because the specification has not provided any variants of these sequences. There is no description of the mutational sites that exist in nature and there is no description of how the structure of SEQ ID NO: 41-49 relates to the structure of any strictly neutral alleles. The general knowledge in the art concerning variants does not provide any indication of how the structure of one allele is representative of unknown alleles. The nature of alleles is such that they are variant structures, and in the present state of the art the structure of one does not provide guidance to the structure of others.

The common attributes are not described. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the genus and is insufficient to support the claim.

Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 7, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Legoux et al. (US Pat. 5,480,800, January 1996).

Legoux et al. (herein referred to as Legoux) teaches a protein sequence comprising a Met (see first aa of SEQ ID NO: 2). The amino acid sequence of SEQ ID NO: 2 is 820 amino acids in length (having a length of at least 15 amino acids). The claims do not currently require that the fragment consists of at least 15 amino acids from SEQ ID NO: 41-49. Thus, Legoux teaches a polypeptide encompassed by the instant claim.

Conclusion

8. No claims allowable.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571) 272-0782.

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J. Goldberg

Jeanine Goldberg
Patent Examiner
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